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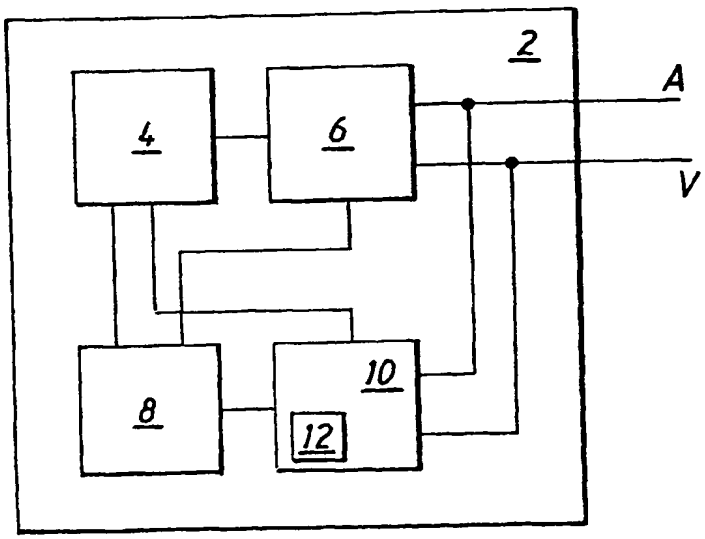
(54) Title: IMPLANTABLE DUAL CHAMBER HEART STIMULATOR



(57) Abstract: The invention relates to an implantable dual chamber heart stimulator (2) comprising a stimulation threshold detector (10) arranged to activate a stimulation threshold search algorithm to perform a stimulation threshold search at predetermined time intervals in order to determine a stimulation threshold of heart tissue. The heart stimulator comprises an AV-interval generator (4) adapted to generate an AV-interval and a control means (8) arranged to temporarily shorten the AV-interval to a threshold search AV-interval when said threshold search is performed. The heart stimulator further comprises AR/PR-interval measurement means (12) adapted to measure the actual AR/PR conduction time wherein said threshold search AV-interval is set by the AV-interval generator (4) and the control means (8) to the measured AR/PR-interval shortened by a predetermined time.

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Implantable dual chamber heart stimulator

Technical field of the invention

The present invention relates to an implantable dual chamber heart stimulator according to the preamble of the independent claim.

Background of the invention

To reduce the energy consumption of heart stimulators, an automatic threshold search function is used to maintain the energy of the stimulation pulses at a level just above that which is needed to effectuate capture.

Figure 1 discloses an IEGM illustrating the principles of threshold search algorithms according to established standard prior art, see e.g. US-5,476,487, and which the present invention is intended to improve. A and V designate atrial and ventricular stimulation pulses, respectively. BU is a high output backup pulse delivered if loss of capture (LOC) occurs. As can be seen (complex 3) the pre-programmed AV-interval is prolonged with Δ when a LOC occurs (complex 2). The reason for that is to await any intrinsic event if the first LOC was the result of a fusion beat. In this case there is no intrinsic activity and the LOC was not a result of a fusion beat but was due to a changed stimulation threshold of the heart tissue, and a stimulation threshold search is initiated. During the threshold search the pre-programmed AV-interval is shortened to "AV-short" to override any intrinsic heart activity. The ventricular stimulation amplitude is successively stepped up by a predetermined amplitude step of e.g. 0,1-0,3 V and each unsuccessful ventricular stimulation pulse is followed by a back-up pulse. As an alternative the ventricular stimulation

amplitude may start at an amplitude above the stimulation threshold and then successively be stepped down until non-capture occurs. This is performed until the stimulation threshold is detected, i.e. capture is detected from the ventricular stimulation pulse, and the stimulation pulse amplitude is then set to a value that equals the stimulation threshold plus a working margin, e.g. 0,3 V.

For the purposes of the discussions and definitions below relating to the invention, it should be noted that the present invention is directed to a dual chamber heart stimulator having, inter alia, an inhibiting function such that, using the commonly accepted terminology, the AV-interval could also be started by an intrinsic atrial heart activity, a P-wave, and the started interval is then a PV-interval. Thus, instead of writing PV/AV-interval is the term AV-interval (AVI) used in this application whenever there is no need to distinguish between the two. The AVI, so far discussed is thus artificial in the sense that it is controlled by an AV-counter in the pacemaker. However, there is also a natural AV interval or AV conduction time, which is related to the physiological conduction pathway in the heart. This interval is also referred to as the PR/AR interval as it starts with either a P-wave or an A-pulse and ends with the natural ventricular depolarisation indicated by an R-wave. Whenever necessary for clarity, the more specific terms just discussed will be used.

Another capture verification method and apparatus for a single chamber or a double chamber implantable pacemaker utilising heart rhythm stability measurements to minimise the likelihood of fusion is disclosed in US-5,766,229.

It is an object of the present invention to provide an improved dual chamber heart stimulator with a dynamic determination of the AV-interval adapted for stimulation threshold searches.

Short description of the inventive concept

According to the invention is the above-mentioned improvement achieved by an implantable heart stimulator according to the independent claim.

Preferred embodiments are set forth in the dependent claims. The claimed dual chamber heart stimulator thus performs threshold searches using an AVI that achieves good hemodynamic of the heart and that avoids fusion.

The present invention is especially applicable when the threshold search is activated at predetermined time intervals due to that the hemodynamic situation of the heart then is more stable compared to threshold searches activated due to loss of capture.

Short description of the appended drawings

Figure 1 discloses an IEGM illustrating a threshold search algorithm applicable in relation with the present invention,

Figure 2 discloses a schematic block diagram of an implantable heart stimulator according to the present invention.

Figure 3 discloses an IEGM showing a part of a heart cycle illustrating the principles of the present invention.

Detailed description of preferred embodiments of the invention.

Figure 2 discloses a schematic block diagram of an implantable dual chamber heart stimulator 2 according to the present invention. The heart stimulator is adapted to be

connected to heart electrode leads that in turn are adapted to be inserted into the atrium A and into the ventricle V of the heart in accordance with established implantation techniques. The heart stimulator comprises an AV interval generator 4, a stimulation pulse generator 6, a control unit 8 and a stimulation threshold detector 10 including an AR/PR interval measurement means 12.

A stimulation threshold search algorithm, preferably in accordance with the algorithm described above, stored in the control unit 8 is activated at predetermined time intervals, e.g. every 8 hour. When the algorithm is activated the AVI is shortened in order to override intrinsic activity.

The programmed AVI is initially set to a value of about 160 ms (so called shipped setting). Some implantable heart stimulators have different values for AVI and PVI (interval started by intrinsic atrial activity, a P-wave) where AVI is longer than PVI, typical values are 170 ms for AVI and 150 ms for PVI. The reason for having different values is to even out the differences in pumping capacity during stimulation and inhibition, respectively. The difference in the duration of these two intervals is referred to as "hysteresis".

As described above the AVI is shortened to AV short during a stimulation threshold search according to a threshold search algorithm in order to override any intrinsic activity.

According to one alternative of a prior art threshold search algorithm is AV short 25 ms or 50 ms dependent on if the atrial activity was intrinsic (PVI) or stimulated (AVI), respectively. According to another alternative is instead the programmed AVI shortened by a predetermined time, e.g. between 30-50 ms.

According to the present invention is the PR/AR conduction time measured. That time is then shortened with a predetermined time to obtain a threshold search AVI. The predetermined time by which the measured time is shortened is 30-50 ms, preferably 40 ms. The PR/AR conduction time measurement is performed in the following way. The PVI/AVI is temporarily prolonged to typically 180/200 ms, respectively, during a small number of heart cycles, typically in the order of five. If it was possible to measure the conduction time the measured conduction time is then used for performing the threshold search as described above. If the conduction time was measured but the resulting threshold search AVI was shorter than a threshold search AVI limit the threshold search is preferably postponed and the conduction measurement is repeated with regular intervals until a conduction time is measured that allows a threshold search to be performed. The threshold search AVI limit is preferably in the range of 80-120 ms, typically 100 ms, but other values are also possible. It should be noted that if a threshold search is postponed due to the fact that the conduction time is too short then there is no need for ventricular pacing (due to the fact that there is intrinsic ventricular activity present) so there is no drawback associated with postponing the threshold search under these conditions.

Another possibility is that it is not possible to measure the conduction time, e.g. due to conduction failures, e.g. AV-blocks. In that case is the programmed AVI shortened with a predetermined value used and checked against the threshold search AVI limit as described above. The PR/AR interval conduction time measurements are performed by the PR/AR interval conduction time measurement means 12 in conjunction

with the AVI generator 4. The evaluation of the result of the measurements are performed by the control means 8.

In Figure 3 is an IEGM disclosed that shows a part of a heart cycle illustrating the principles of the present invention.

As can be seen is a prolonged AVI (AVI-L) started when an atrial stimulation pulse A is applied. Intrinsic ventricular activity R that occurs during the prolonged AVI is detected and the actual AR conduction time (AR) is measured by the PR/AR-interval measurement means. When a threshold search then is performed is a threshold search AVI (TS-AVI) set by the AV-interval generator and the control means to the measured AR shortened by a predetermined time (t).

Many different types of threshold searches are possible. According to a preferred threshold search, as shortly described above, will the search start at the present ventricular stimulation amplitude with two stimuli and then decrease the amplitude for the following two stimuli and so on until a loss of capture is found. When a loss is found then the amplitude is increased for two stimuli. If these stimuli result in capture then the stimulation threshold is found. A working margin might be added to the threshold to obtain the ventricular stimulation amplitude in accordance with established technique.

It should however be noted that the threshold search AVI determined according to the present invention is applicable to any threshold search algorithm.

The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above

embodiments should not be taken as limiting the scope of the invention, which is defined by the appendant claims.

Claims

1. Implantable dual chamber heart stimulator (2) comprising a stimulation threshold detector (10) arranged to activate a stimulation threshold search algorithm to perform a stimulation threshold search at predetermined time intervals in order to determine a stimulation threshold of heart tissue, an AV-interval generator (4) adapted to generate an AV-interval and a control means (8) arranged to temporarily shorten the AV-interval to a threshold search AV-interval (TS-AVI) when said threshold search is performed, characterized in that said heart stimulator further comprises AR/PR-interval measurement means (12) adapted to measure the actual AR/PR conduction time (AR) wherein said threshold search AV-interval is set by the AV-interval generator (4) and the control means (8) to the measured AR/PR-interval shortened by a predetermined time (t).

2. Heart stimulator according to claim 1, characterized in that said predetermined time is set to 30-50 ms, preferably 40 ms, by said control means (8).

3. Heart stimulator according to claim 1, characterized in that said AV-interval generator is made, by said control means (8), to temporarily prolong the AV-interval (AVI-L) a predetermined number of heart cycles in order to perform said measurement of the actual AR/PR conduction time.

4. Heart stimulator according to claim 3, characterized in that said prolonged AV-interval is 180-200 ms.

5. Heart stimulator according to claim 3 or 4, characterized in that said predetermined number of heart cycles is 4-7, preferably 5.

6. Heart stimulator according to any preceding claim, characterized in that said AV-interval generator (4) is provided with a predetermined permanently programmed AV-interval.

Fig. 1

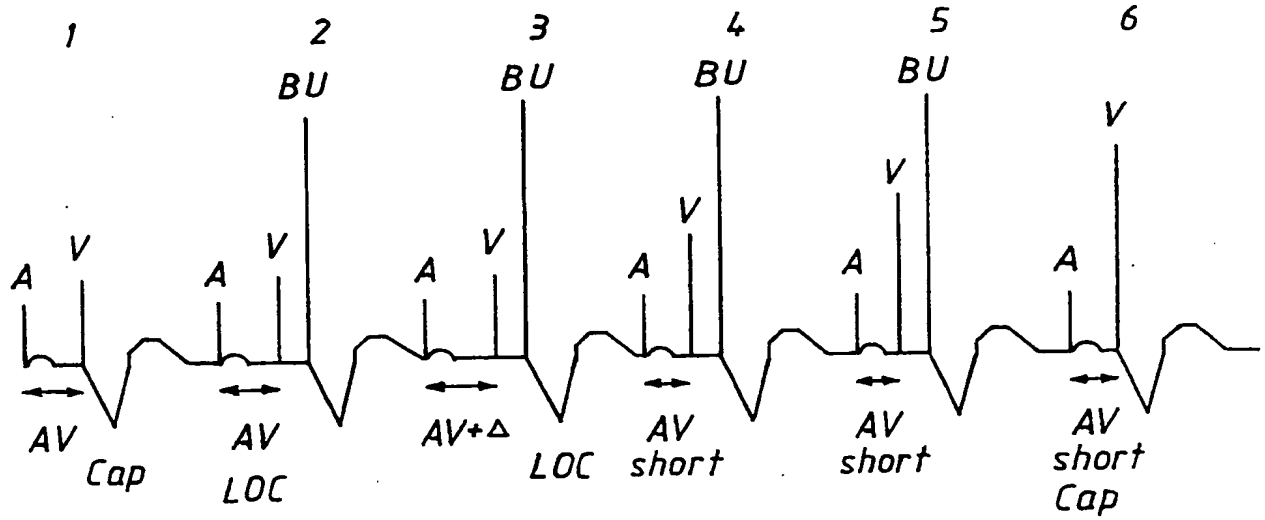
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Fig. 2

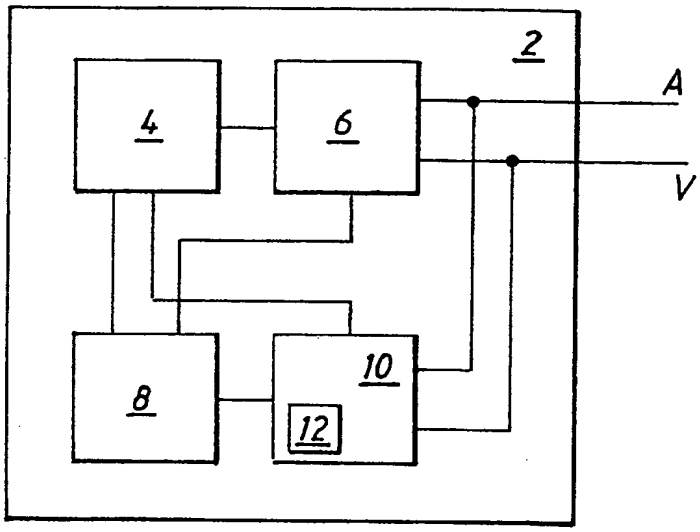
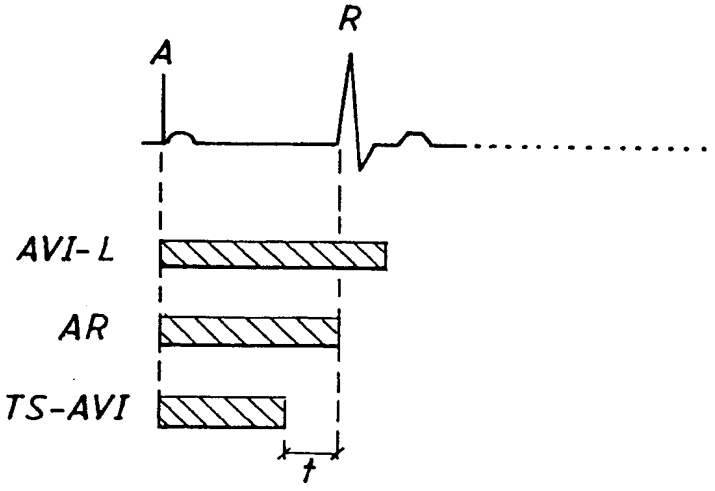


Fig. 3



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01903

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/37
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9604956 A2 (MEDTRONIC, INC.), 22 February 1996 (22.02.96), page 17, line 11 - line 15; page 19, line 1 - line 26, abstract --	1-6
A	WO 9524944 A1 (MEDTRONIC, INC.), 21 Sept 1995 (21.09.95), page 3, line 15 - line 21, abstract --	1-6
D,A	US 5476487 A (J.A. SHOLDER), 19 December 1995 (19.12.95), abstract --	1-6
D,A	US 5766229 A (G.A. BORNZIN), 16 June 1998 (16.06.98), abstract --	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search	Date of mailing of the international search report
3 January 2001	13 -02- 2001
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nikolaj Hautaviita/AE Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9604956 A2	22/02/96	AU 694258 B	16/07/98
		AU 3205795 A	07/03/96
		CA 2196430 A	22/02/96
		DE 69509659 D,T	30/12/99
		EP 0776233 A,B	04/06/97
		SE 0776233 T3	
		EP 0850662 A	01/07/98
		JP 10503956 T	14/04/98
		US 5601615 A	11/02/97
		US 5861012 A	19/01/99
WO 9524944 A1	21/09/95	AU 681942 B	11/09/97
		AU 1743195 A	03/10/95
		DE 69510448 D,T	24/02/00
		EP 0751804 A,B	08/01/97
		SE 0751804 T3	
		JP 2804373 B	24/09/98
		JP 9504982 T	20/05/97
		US 5507782 A	16/04/96
US 5476487 A	19/12/95	EP 0719569 A	03/07/96
US 5766229 A	16/06/98	EP 0872260 A	21/10/98